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## SUBSTITUTE SENATE BILL 6632

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State of Washington 59th Legislature 2006 Regular Session

By Senate Committee on Health & Long-Term Care (originally sponsored by Senators Kastama, Eide, Keiser, Roach, Johnson, Regala, Fraser, Haugen, Kline, Hewitt, Swecker, Finkbeiner, McAuliffe, Poulsen and Spanel)

READ FIRST TIME 02/03/06.

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AN ACT Relating to Washington state participation in the Johns
Hopkins Atlantic cardiovascular patient outcomes research team elective
angioplasty study to determine, through evidence-based medicine,
whether nonemergency percutaneous coronary interventions can be
performed safely and effectively at hospitals without on-site open
heart surgery programs; amending RCW 70.38.105; adding new sections to
chapter 70.38 RCW; and providing an expiration date.

## 8 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

- NEW SECTION. Sec. 1. (1) The legislature finds that the current system in this state of allowing hospitals without on-site open heart surgery programs to perform emergency but not nonemergency angioplasty and stent placements, also known as percutaneous coronary intervention, is an inefficient system and is impacting access to and quality of cardiac services in many communities throughout the state. Negative consequences of the current system include:
- (a) An inability for many communities to recruit and retain cardiologists resulting in a shortage of cardiologists that impacts the availability, accessibility, and quality of comprehensive cardiac services;

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1 (b) Duplication of diagnostic tests, evaluations, and other 2 procedures, which leads to increased patient risk; and

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- (c) Higher costs associated with duplication, transfers, and longer hospital stays.
- (2) While advancements in technology have expanded the availability 5 of nonemergency percutaneous coronary interventions at many hospitals 6 7 without on-site open heart surgery programs both nationally and internationally, Washington state only allows hospitals without on-site 8 surgery programs 9 heart to perform percutaneous 10 interventions on an emergency basis. The number of hospitals performing nonemergency percutaneous coronary interventions without 11 12 on-site open heart surgery programs continues to grow in the United These interventions are also being performed in every 13 States. industrialized country in Europe, and this practice is approved by the 14 European society for cardiology. Despite this growing trend, concerns 15 16 regarding whether nonemergency percutaneous coronary interventions can 17 be performed safely and effectively in hospitals without on-site open heart surgery programs continue to be raised because existing data is 18 gathered from registries, not randomized trials. 19
  - (3) The Johns Hopkins cardiovascular patient outcomes research team elective angioplasty study, conducted in partnership with nationally renowned cardiologists and researchers from the nation's top research institutions, is a randomized clinical trial comparing nonemergency percutaneous coronary interventions performed at hospitals with and without on-site open heart surgery programs. The Johns Hopkins study is designed to gather the highest quality evidence-based data to answer the concerns raised.
  - (4) It is the intent of the legislature that Washington state allow qualified hospitals to participate in the Johns Hopkins study, without certificate of need review. The study will ensure that future decisions on cardiac service delivery in Washington are made on evidence-based data, and where possible, such data shall include data specific to Washington state. The legislature finds that participation in the study is in the best interests of our citizens.
- NEW SECTION. Sec. 2. (1) As used in sections 1 through 3 of this act and RCW 70.38.105, "Johns Hopkins study" means the Johns Hopkins

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cardiovascular patient outcomes research team elective angioplasty study.

- (2) The department, in selecting Washington state hospitals to participate in the Johns Hopkins study, shall require that each hospital:
- (a) Develop and maintain an agreement with another hospital that has an existing on-site open heart surgery program and agrees to accept emergency and nonemergency transfers of patients for additional intervention, cardiac surgery, or other medical care from the participating hospital;
- (b) Develop and maintain agreements with emergency transfer or ambulance services capable of providing advanced life support, including an intra-aortic balloon pump;
- (c) Currently operate an emergency percutaneous coronary intervention program;
- (d) Demonstrate the ability to perform a minimum of two hundred nonemergency and emergency percutaneous coronary interventions per year. Hospitals shall provide documentation on current diagnostic catheterization procedures and emergency percutaneous coronary intervention volumes, as well as current cardiologist procedure volumes. The department shall, in consultation with Johns Hopkins, determine if the documentation is sufficient to meet this criterion; and
- (e) Meet all Johns Hopkins study criteria, be accepted for participation in the Johns Hopkins study, and agree to abide by the Johns Hopkins study protocols.
- (3) The department, in consultation with Johns Hopkins, shall not approve any hospital to participate in the Johns Hopkins study if:
- (a) Participation would reduce the number of emergency and nonemergency percutaneous coronary interventions at any hospital with an existing open heart surgery program that currently performs more than three hundred total interventions annually to below three hundred interventions per year;
- (b) Participation would reduce the number of emergency and nonemergency percutaneous coronary interventions at any hospital with an existing open heart surgery program that currently performs less than three hundred emergency and nonemergency percutaneous coronary

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interventions annually to below two hundred twenty interventions per year; or

- (c) Another hospital located within a two-mile radius of a hospital being considered for participation submits a written objection to such participation.
- (4) Any hospital that meets the requirements of this section shall be selected by the department for participation in the Johns Hopkins study up to a maximum of three. If qualified, at least one hospital shall be from a rural area.
- (5) Those hospitals selected to participate in the Johns Hopkins study shall be allowed to perform nonemergency percutaneous coronary interventions without on-site open heart surgery programs and shall not be subject to the certificate of need review requirements in RCW 70.38.105 (3) and (4) only for the specific time period and purpose of the Johns Hopkins study. This limited exemption from certificate of need review is in the public interest and is necessary to the conduct of the study.
- (6) The department shall monitor the outcomes of the Johns Hopkins study, obtain quarterly reports from Johns Hopkins, and send those reports to the chairs of the house of representatives and senate health committees.
- (7) The department may terminate any hospital's participation in the study if, after consultation with Johns Hopkins, it finds that the hospital's participation is endangering the health and safety of Washington citizens. The department may also terminate Washington state participation in the Johns Hopkins study if, after consultation with Johns Hopkins, it finds that the study is endangering the health and safety of Washington citizens.
- NEW SECTION. Sec. 3. The department shall require hospitals participating in the Johns Hopkins study to submit an application fee to the department to cover appropriate costs, not covered by the Johns Hopkins study, for the administration of the Johns Hopkins study by the department.
- **Sec. 4.** RCW 70.38.105 and 2004 c 261 s 6 are each amended to read as follows:

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1 (1) The department is authorized and directed to implement the 2 certificate of need program in this state pursuant to the provisions of 3 this chapter.

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- (2) There shall be a state certificate of need program which is administered consistent with the requirements of federal law as necessary to the receipt of federal funds by the state.
- (3) No person shall engage in any undertaking which is subject to certificate of need review under subsection (4) of this section without first having received from the department either a certificate of need or an exception granted in accordance with this chapter.
- (4) Except for nonemergency percutaneous coronary interventions performed at hospitals selected by the department to participate in the Johns Hopkins study as provided in sections 1 through 3 of this act, the following shall be subject to certificate of need review under this chapter:
- 16 (a) The construction, development, or other establishment of a new 17 health care facility;
- 18 (b) The sale, purchase, or lease of part or all of any existing 19 hospital as defined in RCW 70.38.025;
  - (c) Any capital expenditure for the construction, renovation, or alteration of a nursing home which substantially changes the services of the facility after January 1, 1981, provided that the substantial changes in services are specified by the department in rule;
  - (d) Any capital expenditure for the construction, renovation, or alteration of a nursing home which exceeds the expenditure minimum as defined by RCW 70.38.025. However, a capital expenditure which is not subject to certificate of need review under (a), (b), (c), or (e) of this subsection and which is solely for any one or more of the following is not subject to certificate of need review:
    - (i) Communications and parking facilities;
- 31 (ii) Mechanical, electrical, ventilation, heating, and air 32 conditioning systems;
  - (iii) Energy conservation systems;
- (iv) Repairs to, or the correction of, deficiencies in existing
  physical plant facilities which are necessary to maintain state
  licensure, however, other additional repairs, remodeling, or
  replacement projects that are not related to one or more deficiency

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citations and are not necessary to maintain state licensure are not exempt from certificate of need review except as otherwise permitted by (d)(vi) of this subsection or RCW 70.38.115(13);

- (v) Acquisition of equipment, including data processing equipment, which is not or will not be used in the direct provision of health services;
- (vi) Construction or renovation at an existing nursing home which involves physical plant facilities, including administrative, dining areas, kitchen, laundry, therapy areas, and support facilities, by an existing licensee who has operated the beds for at least one year;
  - (vii) Acquisition of land; and
- 12 (viii) Refinancing of existing debt;

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- (e) A change in bed capacity of a health care facility which increases the total number of licensed beds or redistributes beds among acute care, nursing home care, and boarding home care if the bed redistribution is to be effective for a period in excess of six months, or a change in bed capacity of a rural health care facility licensed under RCW 70.175.100 that increases the total number of nursing home beds or redistributes beds from acute care or boarding home care to nursing home care if the bed redistribution is to be effective for a period in excess of six months. A health care facility certified as a critical access hospital under 42 U.S.C. 1395i-4 may increase its total number of licensed beds to the total number of beds permitted under 42 U.S.C. 1395i-4 for acute care and may redistribute beds permitted under 42 U.S.C. 1395i-4 among acute care and nursing home care without being subject to certificate of need review. If there is a nursing home licensed under chapter 18.51 RCW within twenty-seven miles of the critical access hospital, the critical access hospital is subject to certificate of need review except for:
- 30 (i) Critical access hospitals which had designated beds to provide 31 nursing home care, in excess of five swing beds, prior to December 31, 32 2003; or
  - (ii) Up to five swing beds.

Critical access hospital beds not subject to certificate of need review under this subsection (4)(e) will not be counted as either acute care or nursing home care for certificate of need review purposes. If a health care facility ceases to be certified as a critical access

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hospital under 42 U.S.C. 1395i-4, the hospital may revert back to the type and number of licensed hospital beds as it had when it requested critical access hospital designation;

- (f) Any new tertiary health services which are offered in or through a health care facility or rural health care facility licensed under RCW 70.175.100, and which were not offered on a regular basis by, in, or through such health care facility or rural health care facility within the twelve-month period prior to the time such services would be offered;
- (g) Any expenditure for the construction, renovation, or alteration of a nursing home or change in nursing home services in excess of the expenditure minimum made in preparation for any undertaking under subsection (4) of this section and any arrangement or commitment made for financing such undertaking. Expenditures of preparation shall include expenditures for architectural designs, plans, working drawings, and specifications. The department may issue certificates of need permitting predevelopment expenditures, only, without authorizing any subsequent undertaking with respect to which such predevelopment expenditures are made; and
- (h) Any increase in the number of dialysis stations in a kidney disease center.
  - (5) The department is authorized to charge fees for the review of certificate of need applications and requests for exemptions from certificate of need review. The fees shall be sufficient to cover the full cost of review and exemption, which may include the development of standards, criteria, and policies.
- 27 (6) No person may divide a project in order to avoid review 28 requirements under any of the thresholds specified in this section.
- NEW SECTION. Sec. 5. Sections 1 through 3 of this act expire 30 December 31, 2010.
- 31 <u>NEW SECTION.</u> **Sec. 6.** Sections 1 through 3 of this act are each 32 added to chapter 70.38 RCW.

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